

meanings for terms either explicitly or by implication. Thus, to help determine the proper construction of a patent claim, a construing court consults the written description, and, if in evidence, the prosecution history. After claim construction, the fact finder compares the properly construed claim with the allegedly infringing devices. Infringement requires the patentee to show that the accused device contains or performs each limitation of the asserted claim, or an equivalent of each limitation not satisfied literally. The sale or manufacture of equipment to perform a claimed method is not direct infringement within the meaning of 35 U.S.C.S. § 271(a).

***Patent Law > Infringement > Claim Interpretation  
Civil Procedure > Jury Trials > Province of Court & Jury***

[HN3] Claim construction is a question of law and is not the province of the jury.

***Patent Law > Infringement > Claim Interpretation***

[HN4] The doctrine of waiver as applied to claim construction prevents a party from offering a new claim construction on appeal. Moreover, a party's objection to a jury instruction is waived unless that party objects to the instruction before the jury retires to consider the verdict. Fed. R. Civ. P. 51.

***Patent Law > Infringement > Acts of Infringement***

[HN5] The law recognizes the irrelevance of apparatus distinctions in determining infringement of process claims.

***Patent Law > Infringement > Claim Interpretation***

[HN6] The ordinary meaning of "to hold" is to keep in position, guide, control, or manage. This meaning also imposes no requirement that an object remain stationary.

***Patent Law > Infringement > Claim Interpretation***

[HN7] The best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention.

***Patent Law > Infringement > Claim Interpretation***

[HN8] In one sense, "to urge" means simply to press or to push. "To urge" may also mean to cause to move, hasten, or gather speed.

***Patent Law > Infringement > Acts of Infringement***

[HN9] The Patent Act imposes indirect infringement liability on a party who actively induces others to directly infringe a patent. 35 U.S.C.S. § 271(b).

***Patent Law > Jurisdiction & Review > Standards of Review***

[HN10] In reviewing a district court's denial of a motion for judgment as a matter of law, an appellate court presumes that the jury resolved all factual disputes in favor of the prevailing party and leaves those findings undisturbed as long as substantial evidence supports them.

***Patent Law > Infringement > Acts of Infringement***

[HN11] Although 35 U.S.C.S. § 271(b) does not use the word "knowingly," the United States Court of Appeals for the Federal Circuit has uniformly imposed a knowledge requirement. The court defined the generally applicable intent standard in Hewlett-Packard, that proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement under § 271(b).

***Patent Law > Infringement > Defenses > Invalidity***

[HN12] The Patent Act erects a presumption of validity for an issued patent. 35 U.S.C.S. § 282 (1994). Therefore, invalidity requires clear and convincing evidence.

***Patent Law > Specification & Claims > Description Requirement***

***Patent Law > Jurisdiction & Review > Standards of Review***

[HN13] A patent specification must contain an adequate written description. 35 U.S.C.S. § 112, P 1 (1994). Whether a specification complies with the written description requirement of § 112, P 1 is a question of fact that is reviewed for substantial evidence.

***Patent Law > Specification & Claims > Description Requirement***

[HN14] The purpose of the written description requirement in 35 U.S.C.S. § 112, P 1 is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. In that setting, the written description is the metric against which a subsequently added claim is measured to determine if it is due the priority date of the original patent.

***Patent Law > Specification & Claims > Description Requirement***

[HN15] The description requirement in 35 U.S.C.S. § 112, P 1 may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

***Patent Law > Specification & Claims > Description Requirement***

[HN16] The test for compliance with 35 U.S.C.S. § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. The possession test requires assessment from the viewpoint of one of skill in the art. The Lilly disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing.

**Patent Law > Specification & Claims > Enablement Requirement**

[HN17] The patent specification must disclose information sufficient to enable those skilled in the art to make and use the claimed invention. 35 U.S.C.S. § 112 P 1. That some experimentation is required to practice the claimed invention is permissible, so long as it is not undue. Enablement under 35 U.S.C.S. § 112, P 1, is a question of law that is reviewed de novo. The court reviews a jury's underlying factual determinations related to enablement for substantial evidence.

**Patent Law > Novelty & Anticipation**

[HN18] Anticipation under 35 U.S.C.S. § 102 requires that a single prior art reference disclose each and every limitation of the claimed invention. A jury's conclusions on anticipation are reviewed for substantial evidence.

**COUNSEL:**

Jon A. Baughman, Pepper Hamilton LLP, of Philadelphia, Pennsylvania, argued for plaintiffs-cross appellants. With him on the brief were Erik N. Videlock and Nicole D. Galli. Of counsel on the brief were Marvin Petry and Linda R. Poteate, Larson & Taylor, of Alexandria, Virginia.

Albert J. Breneisen, Kenyon & Kenyon, of New York, New York, argued for defendant-appellant. With him on the brief were John W. Bateman and Sheila Mortazavi.

**JUDGES:**

Before RADER, SCHALL, and BRYSON Circuit Judges. Concurring opinions filed by Circuit Judges RADER, and BRYSON.

**OPINION:**

**PER CURIAM.**

At trial, a jury in the United States District Court for the Eastern District of Pennsylvania found that Moba, B.V., Staalkat, B.V., and FPS Food Processing Systems, Inc. (collectively FPS) did not infringe patents assigned to Diamond Automaton, Inc. (Diamond). See *Moba, B.V. v. Diamond Automaton, Inc.*, No. 95-CV-2631, 2000 U.S. Dist. LEXIS 15483, at \*43 (E.D. Pa. Sept. 29,

2000). In response to a motion for judgment as a matter of [\*2] law (JMOL), the district court correctly discerned that substantial evidence supports the jury's verdict that machines sold by FPS and used by its customers do not practice the method of United States Patent No. 4,519,494 ('494 patent). However, no reasonable jury could find that machines sold by FPS and used by its customers do not practice the method of United States Patent No. 4,519,505 ('505 patent). Thus, this court affirms-in-part, reverses-in-part, and remands for a determination of damages.

**I.**

Diamond is a Michigan corporation that manufactures and sells high-speed egg processing machines to sort batches of eggs into different categories by weight and quality. Diamond developed these machines during the early 1980s with technology that significantly increased the processing speed for eggs. Diamond obtained various patents covering aspects of that technology, including the '494 and '505 patents, and United States Patent Nos. 4,569,444 ('444 patent) and 4,505,373 ('373 patent). While Diamond asserted all of these patents at trial, only the '505 and '494 patents appear in this appeal. The '505 patent relates generally to "front end" processing of eggs, while the '494 patent [\*3] relates generally to "back end" processing of eggs.

The "front end" process first washes the eggs, then introduces them into a candling station where a high intensity light source checks the eggs for defects such as blood spots or cracks. The process then weighs the eggs. A computer stores this information for use in sorting the eggs at a later point. Figure 2 of the '505 patent illustrates an embodiment of the invention designed to weigh eggs and to lift them to an overhead conveyor.

[SEE FIGURE 2 IN ORIGINAL]

Claim 24 of the '505 patent corresponds generally to the subject matter of Fig. 2:

24. A method for advancing a plurality of rows of eggs from a candling station through a plurality of weighing stations in an egg grading apparatus, comprising,

conveying eggs from said candling station to elongated guide means disposed adjacent to said candling station,

continuously advancing said eggs on said guide means through said weighing stations,

simultaneously with said step of advancing, weighing said eggs at said weighing stations,

guiding said eggs from said weighing stations first to a plurality of egg holding stations located downstream of

said guide means and [\*4] then to a plurality of locations longitudinally spaced-apart from and substantially horizontally co-planar with said holding stations,

guiding further eggs to said plurality of holding stations, and lifting said eggs simultaneously from said holding stations and said plurality of longitudinally spaced-apart locations.

'505 patent, col. 13, ll. 33-54 (emphasis added).

The "back end" process receives eggs from "front end" processing and transfers them to an overhead conveyor. This conveyor carries the eggs in rows until dropping off each individual egg at a different receiving station based on the information in the computer. At each station, the eggs are either packaged or discarded. Figure 8 of the '494 patent illustrates an embodiment of the invention designed to receive eggs from an overhead conveyor for transport to a packer:

[SEE FIGURE 8 IN ORIGINAL]

Claim 28 of the '494 patent corresponds generally to the subject matter of Fig. 8:

28. A method of transferring eggs delivered in spaced-apart aligned relationship by a first conveyor means to a receiving station, comprising the steps of,

delivering eggs to said receiving station in parallel spaced apart [\*5] rows on said first conveyor means,

releasing eggs from said first conveyor means at the receiving station in accordance with a predetermined requirement,

positioning a receiving means below the first conveyor means so as to receive therein and deliver to a common member the eggs released from the parallel spaced-apart rows of the first conveyor means,

receiving said eggs in the receiving means disposed at said receiving station whereby the released eggs from both said parallel spaced apart rows of eggs fall on and are received by said receiving means,

rotating the receiving means downwardly and away from said first conveyor means to urge the received eggs downwardly,

guiding said eggs received in said receiving means downwardly and away from said receiving means, and

conveying said eggs away from said receiving means on second conveyor means,

said step of releasing comprising releasing said eggs successively from said first conveyor means at said

receiving station along the length of said receiving means, and said step of conveying comprising conveying said eggs individually in rows away from said receiving means on said second conveyor means.

'494 patent, col. [\*6] 12, ll. 9-40 (emphasis added).

Moba, B.V., and Staalkat, B.V., are Dutch companies that also manufacture and sell high-speed egg processing machines, such as the Moba Omnia and the Staalkat Selecta. FPS Food Processing, a Pennsylvania corporation, sells Moba's and Staalkat's egg processing machines in the United States. In the United States market, FPS and Diamond are the only significant competitors in the manufacture and sale of high-speed egg processing machines.

In 1994, Diamond filed a patent infringement suit in the United States District Court for the Eastern District of Michigan against FPS. The district court dismissed that case for lack of personal jurisdiction. In 1995, FPS filed suit in the United States District Court for the Eastern District of Pennsylvania seeking a declaratory judgment that the '444, '494, '373, and '505 patents are invalid and not infringed by the Moba Omnia and the Staalkat Selecta. Diamond filed a declaratory judgment counterclaim that the patents are valid and infringed. After discovery, the district court construed the patent claims. Then a jury heard the case from January 28, 2000 to February 25, 2000. On February 22, 2000, before the jury retired [\*7] to consider its verdict, Diamond moved for entry of JMOL under *Rule 50(a) of the Federal Rules of Civil Procedure* that FPS infringed and induced infringement of the four patents. In its February 25, 2000 verdict, the jury found that those patents were not invalid and not infringed. On March 6, 2000, the district court denied Diamond's February 22, 2000 JMOL motion, and entered judgment in favor of Diamond on the validity issues and in favor of FPS on the infringement issues. Diamond renewed its motion for JMOL regarding infringement, which the district court again denied.

Diamond argues that claim 24 of the '505 patent and claim 28 of the '494 patent cover methods used in both the Moba Omnia and the Staalkat Selecta. Diamond also contends that FPS has induced its customers to infringe those claims by selling them the Moba Omnia and the Staalkat Selecta and by training them to use those machines. Diamond appeals, therefore, the district court's denial of JMOL on these issues. FPS cross-appeals the jury's determination that claim 24 of the '505 patent and claim 28 of the '494 patent are not invalid. Because Diamond no longer pursues any claims arising from the '444 or '373 patents, [\*8] or claim 34 of the '494 patent, this court need not address those questions. This court

has jurisdiction over the present appeal under 28 U.S.C. § 1295(a)(1) (2000).

## II.

[HN1] This court reviews claim construction without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1172 (Fed. Cir. 1998) (en banc). This court accords substantial deference to a jury's factual application of a claim construction to the accused device in an infringement determination. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1348-49, 55 USPQ2d 1161, 1164 (Fed. Cir. 2000).

This court reviews a district court's denial of JMOL without deference, reversing only if substantial evidence does not support a jury's factual findings or if the law cannot support the legal conclusions underpinning the jury's factual findings. *Cybor Corp.*, 138 F.3d at 1454. "A district court may overturn a jury's verdict only if upon the record before the jury, reasonable jurors could not have reached that verdict." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353, 61 USPQ2d 1193, 1197 (Fed. Cir. 2001). [\*9]

[HN2] Claim language defines claim scope. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121, 227 USPQ 577, 586 (Fed. Cir. 1985) (en banc). As a general rule, claim language is given the ordinary meaning of the words in the normal usage of the field of the invention. *Toro Co. v. White Consol. Indus.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). Nevertheless, the inventor may act as his own lexicographer and use the specification to supply new meanings for terms either explicitly or by implication. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d 1321, 1330 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 38 USPQ2d 1461, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Thus, to help determine the proper construction of a patent claim, a construing court consults the written description, and, if in evidence, the prosecution history. *Id.* at 979-80.

After claim construction, the fact finder compares the properly construed claim with the allegedly infringing devices. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1360, 54 USPQ2d 1308, 1312 (Fed. Cir. 2000). [\*10] Infringement requires the patentee to show that the accused device contains or performs each limitation of the asserted claim, *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211, 48 USPQ2d 1010, 1014-15 (Fed. Cir. 1998), or an equivalent of each limitation not satisfied literally. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997). The sale or manufacture of equipment to perform a claimed method is not direct infringement within the meaning of 35 U.S.C. § 271(a).

*Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1579, 28 USPQ2d 1081, 1100 (Fed. Cir. 1993).

In this case, the record shows that FPS's customers use the method of the Moba Omnia to process eggs in the United States. Hence, to show infringement Diamond needs only to prove that the Moba Omnia performs the method of claim 24 when it processes eggs.

### "guiding steps"

Based upon its claim construction, the district court instructed the jury, in relevant part, that the guiding steps of claim 24 "are defined as follows: (1) Carrying eggs to holding stations; (2) Carrying eggs from the holding stations [\*11] to the spaced apart location; and (3) Carrying more eggs to the holding stations." At trial, Diamond did not object to either the district court's construction of "guiding steps" or to the jury instructions about that term. Following the jury verdict of non-infringement, the district court denied Diamond's JMOL motion. In its denial, the district court acknowledged that its interpretation of guiding steps left undetermined whether the claim requires sequential performance of the steps. Then the trial court reasoned that the jury reasonably could have determined from the testimony presented that sequential performance is a necessary characteristic of the "guiding steps." The district court's instructions to the jury did not require sequential performance. In essence, the district court allowed the jury to add an additional limitation to the district court's construction of "guiding steps." In this, the district court erred. [HN3] Claim construction is a question of law and is not the province of the jury. *Markman*, 52 F.3d at 979.

This error takes on significance in this appeal because the jury found that the Moba Omnia does not infringe. The record before us discloses no [\*12] alternative basis upon which a reasonable jury could find that the Moba Omnia does not infringe, other than that the Moba Omnia does not satisfy the guiding steps limitation. Thus, by allowing the jury to import an additional limitation into the claims, the district court fundamentally altered the verdict.

Because Diamond did not object to the district court's claim construction or instructions to the jury, FPS contends that Diamond has waived its right to argue the interpretation of "guiding steps" on appeal. [HN4] The doctrine of waiver as applied to claim construction prevents a party from offering a new claim construction on appeal. *Interactive Gift Express v. Compuserve Inc.*, 256 F.3d 1323, 1346, 59 USPQ2d 1401, 1418 (Fed. Cir. 2001). Moreover, a party's objection to a jury instruction is waived unless that party objects to the instruction before the jury retires to consider the verdict. *Fed. R. Civ. P. 51*. In this case, however, waiver does not bar Diamond's argument. Diamond does not now contest the

district court's instruction to the jury on the meaning of "guiding steps." Essentially Diamond does not wish to alter the district court's claim construction on appeal, [\*13] but seeks enforcement of the trial court's claim construction.

Diamond has argued consistently, in its JMOL motions and in its argument on appeal here, that "neither the language of the claim itself nor the Court's order defining this language requires that the 'guiding steps' occur separately." Thus, Diamond has consistently protested the error that this court currently reviews on appeal. Thus, this court will not apply waiver to prevent Diamond from protecting the original breadth of the binding claim construction presented by the district court to the jury from post facto imposition of an additional limitation. *Interactive Gift Express*, 256 F.3d at 1346. Application of waiver in this case would essentially render unreviewable the district court's error. In sum, Diamond has not waived its argument that the guiding steps may be performed simultaneously.

Nowhere does the plain language of claim 24 require separate and consecutive performance of the various guiding steps. Rather, such a construction is contrary to the teachings of the '505 patent. For example, the specification explicitly describes simultaneous performance of guiding steps two and three. '505 [\*14] patent, col. 5, l. 54 to col. 6, l. 3. Moreover, simultaneous performance of the guiding steps is consistent with operating at a significant rate of speed, a stated object of the invention. '505 patent, col. 2, ll. 3-7. The prosecution history is also consistent with this claim construction. Hence, this court, like the district court as well, construes the guiding steps to include simultaneous performance.

FPS argues that, irrespective of whether claim 24 allows simultaneity, the method practiced by the Moba Omnia cannot infringe literally because it does not perform entirely at least one of the required guiding steps. This argument simply repackages FPS's argument for sequential performance of the guiding steps. FPS's argument focuses on distinctions between the Moba Omnia and the patentee's preferred embodiment for the claim 24 method. This court has discredited an infringement analysis for method claims that examines distinctions between implementing apparatuses. *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482, 221 USPQ 649, 653 (Fed. Cir. 1984) [HN5] ("The law recognizes the irrelevance of apparatus distinctions in determining infringement of process claims."). [\*15]

Like the device of Fig. 2, the Moba Omnia lifts eggs to an overhead conveyor for transport. To position the eggs for lifting, the Moba Omnia employs a continuously moving transport conveyor that slows without stopping as each egg passes under the overhead conveyor. In these

actions, the Moba Omnia practices all three guiding steps. With a focus on the movement of the eggs (the subject matter of the method claim) in the Moba Omnia, rather than the movement of the Moba Omnia itself, each of these steps is evident. As required by the first guiding step of claim 24, the Moba Omnia moves a first egg to a holding station. The Moba Omnia then moves the first egg to a spaced-apart location, the second guiding step. Simultaneously, the Moba Omnia moves a second egg to the holding station to perform the third guiding step. The first and second eggs are then ready for simultaneous lifting. In sum, the record evidence provides no basis upon which a reasonable jury could find that the Moba Omnia does not perform the three guiding steps of the '505 patent's claim 24.

#### "holding station"

The district court correctly construed the "holding station" of claim 24 of the '505 patent as "a first location [\*16] in space to which an egg is moved and at which the egg may maintain position until the egg is lifted simultaneously with an egg at a 'spaced-apart location.'" Nonetheless, FPS argues that the district court's construction requires that an egg cease motion before the lift to the overhead conveyor. The claims simply do not require a specific temporal limitation associated with the term "holding." Indeed the specification states that the holding station positions an egg relative to the overhead conveyor for pick-up to the overhead conveyor. See, e.g., '505 patent, col. 2, ll. 44-58, col. 6, ll. 4-8. The specification actually speaks of eggs that are "held" as they move. Id. at col. 5, ll. 2-6 ("The disks each include a plurality of peripheral recesses which are disposed in horizontal alignment so as to receive and hold eggs advanced along the guide bars as they are transferred to the holding stations."). Moreover, [HN6] the ordinary meaning of "to hold" is "to keep in position, guide, control, or manage." The Oxford English Dictionary (2d ed. 1989). This meaning also imposes no requirement that an object remain stationary.

Moreover, as this court has repeatedly counseled, [HN7] the [\*17] best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention. *Markman*, 52 F.3d at 986. In this instance, the context is the swift and safe movement of eggs. As indicated by the specification, the process holds the egg at the same time it moves the egg, thus achieving the dual goals of precision and speed. The process may hold and move an egg at the same time. In sum, the district court correctly construed the term "holding." The term "holding station" also does not require lack of motion.

To show that the Moba Omnia does not include a holding station, FPS relies entirely upon evidence that

eggs in the Moba Omnia do not stop before they are picked up. As described above, however, the claim does not require a stationary holding station. To satisfy the holding station requirement, the Moba Omnia needs only employ "a first location in space to which an egg is moved and at which the egg may maintain position until the egg is lifted simultaneously with an egg at a 'spaced-apart location,'" whether or not eggs stop before the pick up. The record shows that the Moba Omnia employs such a first location. In view of [\*18] the undisputed record evidence, no reasonable jury could find that the Moba Omnia does not move an egg to a holding station as claimed.

In sum, the evidence of record consistent with the correct claim construction shows that the method performed by the Moba Omnia includes all three "guiding steps" and that the Omnia moves eggs to a "holding station." Because no reasonable jury could find on the record evidence that the method performed by the Moba Omnia does not infringe literally and directly claim 24 of the '505 patent, the district court erred in not granting JMOL on that issue.

B.

Turning to claim 28 of the '494 patent, the parties dispute the district court's construction of the limitation "predetermined sequence" and two limitations containing the phrase "downwardly and away." Because construction of the first "downwardly and away" limitation disposes of the question of infringement, this court need not address the other limitations.

The first "downwardly and away" limitation recites: "rotating the receiving means downwardly and away from said first conveyor means to urge the received eggs downwardly." The district court construed this claim language: "The receiving [\*19] means \* must be rotated downwardly (i.e. toward the ground) and be rotated away from the main egg-carrying conveyor from which the eggs are released." With some slight clarification, the district court construed this claim limitation correctly. The slight clarification notes that the limitation constrains the motion of the received eggs as well as the motion of the receiving means. Specifically, the first "downwardly and away" limitation also requires that the receiving means move the eggs downwardly.

\* The district court determined that the language "receiving means" does not invoke § 112, P 6. As the district court's failure to construe this limitation as means-plus-function is not disputed by the parties, this court offers no judgment on the correctness of that determination.

The claim recites that the receiving means "urges the received eggs downwardly." The patent does not explicitly define "urge." [HN8] In one sense, "to urge" means simply to press or to push. See, e.g., The Oxford English Dictionary [\*20] (2d ed. 1989). This meaning of "urge," however, would place the preferred embodiment outside the claim scope. *Vitronics*, at 1583 (a claim interpretation that puts the preferred embodiment outside the claim is "rarely, if ever, correct and would require a highly persuasive evidentiary support."). Moreover this definition of "urge" makes infringement depend on the downward force exerted on the eggs by the rotating receiving means. A receiving means, such as that shown in Fig. 4 of the '494 patent, may rotate downward slowly and support the received eggs against the force of gravity. In doing so, the downward rotation would exert an upward force on the received eggs, i.e., it would "urge" the received eggs upward rather than downward as claim 28 requires. The patent does not show, however, that the downward force is a defining limitation.

Another ordinary meaning of "to urge" avoids exclusion of the preferred embodiment from the claims. Specifically, "to urge" may mean "to cause to move, hasten, or gather speed." The Oxford English Dictionary (2d ed. 1989). This definition receives support from the patent specification. The specification clarifies that "to urge" means broadly [\*21] to move or to carry and that the receiving means may slow the motion of the eggs. For example, the patent specification notes that the receiving means "reduces the speed at which the eggs fall and gently moves the eggs downwardly and outwardly away from carriage assemblies." '494 patent, col. 5, ll. 55-57 (emphases added); see also *Id.* col. 6, ll. 64-64, col. 7, ll. 1-3. Thus, in the context of this patent, this court employs the broader meaning of "to urge," namely, to cause to move.

The Staalkat Selecta employs a brush belt to receive eggs, as shown below. Once the brush belt receives the eggs, it transports the eggs horizontally to a comb mechanism that lifts the eggs from within the bristles of the brush belt. The comb then guides the eggs downward to a second transport conveyor.

[SEE ILLUSTRATION IN ORIGINAL]

At trial, FPS presented substantial evidence that the brush belt of the Staalkat Selecta does not move the eggs downwardly as required by the literal language of claim 28. FPS also presented substantial evidence to support that the Staalkat Selecta does not infringe claim 28 under the doctrine of equivalents. For example, Dr. Kirk, an expert witness for FPS, [\*22] testified that the Selecta's brush belt does not guide eggs downwardly. Rather, the brush guides eggs over a linear path rather than a curved

path. As a result, the eggs moved upward rather than downward relative to their initial position upon receipt in the brush belt. This evidence supports the jury's verdict of no infringement. Even applying the doctrine of equivalents, the Staalkat Selecta performs a different function in a different way to obtain a different result from the language of the claim limitation. Thus, substantial evidence supports the jury's finding that the Staalkat Selecta's method does not satisfy the first "downwardly and away" limitation of claim 28, either literally or under the doctrine of equivalents. Hence, this court affirms the district court's denial of JMOL. Because the Staalkat Selecta does not satisfy the first "downwardly and away" limitation, this court need not reach other potential grounds to support the jury's verdict.

### III.

[HN9] The Patent Act imposes indirect infringement liability on a party who actively induces others to directly infringe a patent. 35 U.S.C. § 271(b) (1994). Diamond appeals the district court's denial of its [\*23] motion for JMOL that FPS indirectly infringes claim 24 of the '505 patent and claim 28 of the '494 patent. [HN10] In reviewing the district court's denial of Diamond's JMOL motion, this court presumes that the jury resolved all factual disputes in favor of the prevailing party and leaves those findings undisturbed as long as substantial evidence supports them. *Sibia Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1354, 55 USPQ2d 1927, 1930 (Fed. Cir. 2000).

The district court denied Diamond's JMOL on inducement because the jury determined that "none of the machines sold by FPS infringe any of the patents in suit." *Moba*, No. 95-CV-2631, 2000 U.S. Dist. LEXIS 15483, at \*43. Because this court upholds the verdict that claim 28 of the '494 patent is not directly infringed, the trial court correctly determined that FPS does not indirectly infringe that claim. *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687, 231 USPQ 474, 477 (Fed. Cir. 1986) ("There can be no inducement of infringement without direct infringement by some party."). However, this court has held that the Moba Omnia method directly infringed claim 24 of [\*24] the '505 patent. Therefore, the issue of infringement by FPS depends on whether FPS "actively induced infringement" within the meaning of 35 U.S.C. § 271(b).

[HN11] Although § 271(b) does not use the word "knowingly," this court has uniformly imposed a knowledge requirement. *Water Tech. Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988); *C.R. Bard, Inc. v. Advanced Card. Sys., Inc.*, 911 F.2d 670, 15 USPQ2d 1540 (Fed. Cir. 1990). This court defined the generally applicable intent standard in

*Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468-69, 15 USPQ2d 1525, 1528-29 (Fed. Cir. 1990). In *Hewlett-Packard*, this court held that "proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement" under § 271(b). *Hewlett-Packard*, 909 F.2d at 1469. *Hewlett-Packard Co. (HP)*, was the assignee of the LaBarre patent on aspects of X-Y plotter technology. *Bausch & Lomb, Inc. (B & L)*, manufactured and sold X-Y plotters and a variety of other electronic equipment through a division that it sold to *Ametek, Inc.* HP [\*25] alleged that B & L induced infringement of the LaBarre patent by its sale to Ametek. This court found, however, that the sale did not evince an intent to induce infringement but, rather, merely an intent to sell at the highest price. This court particularly noted that B & L had no interest in, nor control over, Ametek's use of the purchased division. Implicit in this court's determination was that Ametek could have employed the purchased division in a wide range of non-infringing activity. Moreover, this court noted that the agreement to develop a non-infringing plotter established, if anything, B & L's intent to avoid any inducement of infringement.

In this case, the only intent required of FPS is the intent to cause the acts that constitute infringement. *Hewlett-Packard*, 909 F.2d at 1469. Although Diamond argues that the record shows that FPS sold its customers the Moba Omnia and trained them to use the infringing method, active inducement is nonetheless a factual inquiry. Accordingly, this court declines to make a determination that no reasonable jury could conclude that FPS did not intend that its customers perform acts that constitute infringement. Therefore, [\*26] this court remands for further inquiry into whether FPS indirectly infringes claim 24 of the '505 patent.

### IV.

[HN12] The Patent Act erects a presumption of validity for an issued patent. 35 U.S.C. § 282 (1994). Therefore, invalidity requires clear and convincing evidence. *Id.*; *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 54 USPQ2d 1673 (Fed. Cir. 2000). Because this court has determined that FPS may infringe claim 24 of the '505 patent, depending on resolution of the inducement issue, this court also addresses FPS's appeal of the jury verdict upholding the validity of that claim. FPS argues that the claim is invalid as anticipated, not enabled, and not adequately described.

#### A.

[HN13] A patent specification must contain an adequate written description. 35 U.S.C. § 112, P 1 (1994). Whether a specification complies with the written description requirement of § 112, P 1 is a



question of fact that this court reviews for substantial evidence. *Advanced Display Sys.*, 212 F.3d at 1281.

FPS argues here that if claim 24 of the '505 patent encompasses lifting eggs from a moving conveyor, as this court [\*27] has determined, then claim 24 must be invalid because the '505 patent specification discloses no such conveyor mechanism. In support of this proposition, FPS cites to this court's decision in *Gentry Gallery, Inc. v. Berklene Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998).

Federal Circuit case law reflects two applications of 35 U.S.C. § 112, P 1. First, in 1967, this court's predecessor inaugurated use of § 112 to prevent the addition of new matter to claims. *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (CCPA 1967). As this court's predecessor noted, "the function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Although the statute proscribes addition of new matter to a specification or claims under § 132, the United States Court of Customs and Patent Appeals decided to police the addition of new matter to claims separately using § 112. *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 325-26 (CCPA 1981). [\*28] This court's predecessor explained that the use of § 132 or § 112 was synonymous because "a rejection of an amended claim under § 132 is equivalent to a rejection under § 112, first paragraph." *Id.* Since then, this court has continued to use § 112 to ensure that a patentee had possession at the time of filing of subject matter subsequently claimed. In this court's most recent application of the written description doctrine, it noted: [HN14] "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330, 65 USPQ2d 1385, 1397 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991)). In that setting, the written description is the metric against which a subsequently added claim is measured to determine if it is due the priority date of the original patent. *Id.* at 1560 [\*29] ("The question raised by these situations is most often phrased as whether the application provides 'adequate support' for the claim(s) at issue; it has also been analyzed in terms of 'new matter' under 35 U.S.C. § 132."); *In re Wright*, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) ("When the scope of a claim has been changed by amendment in

such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of § 112, first paragraph.").

In *Gentry Gallery*, the patentee described in the specification a sectional sofa with a center console including recliner controls. The specification as filed clearly identified the console as the only possible location for the controls. From the specification, it was clear that the patentee considered placement of the controls in the center console "to be an essential element of his invention." *Gentry Gallery*, 134 F.3d at 1479. [\*30] Hence, this court limited the scope of the patentee's claims to a sofa with controls located in a center console: "Accordingly, [the patentee's] original disclosure serves to limit the permissible breadth of his later-drafted claims." *Id.* at 147 (emphasis added). Thus, because *Gentry Gallery* applied § 112, P 1, to hold the patentee to the scope of its original filing, it does not apply in this case where FPS made no allegation at all that the disclosure of the '505 patent did not show possession of a later-filed claim.

The second application of the written description requirement is reflected in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). There, this court invoked the written description requirement in a case without priority issues. Invoking § 112, Lilly required a precise definition of a DNA sequence in the patent specification. In more recent cases, however, this court has distinguished Lilly. For instance, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002), neither the specification nor the deposited biological material recited [\*31] the precise "structure, formula, chemical name, or physical properties" required by Lilly. *Id.* at 1324 (quoting Lilly, 119 F.3d at 1566). Although this court initially determined that the specification in Enzo did not satisfy the Lilly disclosure rule, it revisited the issue and remanded to the district court. The court instructed:

On remand the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims.

*Enzo*, 296 F.3d at 1328. Similarly, in this court's most recent pronouncement, it noted:



More recently, in *Enzo Biochem*, we clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, [HN15] the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

*Amgen*, 314 F.3d at 1332. [\*32]

[HN16] The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. See *Vas-Cath*, 935 F.2d at 1561 ("Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation"). The possession test requires assessment from the viewpoint of one of skill in the art. *Id.* at 1563-64 ("the applicant must ... convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention") (emphasis in original); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'" (citation omitted)). In *Enzo* [\*33] and *Amgen*, the record showed that the specification that taught one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention. Similarly in this case, the Lilly disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing.

Accordingly, substantial evidence supports the jury's finding that the '505 patent is not invalid for lack of an adequate written description. The '505 patent specification describes every element of claim 24 in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the invention at the time of filing. FPS's contention that the '505 patent does not adequately disclose lifting eggs from a moving conveyor merely revives its non-infringement argument in the cloak of a validity challenge. As noted, the jury found that one of skill in the art would discern possession of the invention at the time of filing, a finding supported by substantial record evidence. Therefore, the trial court correctly determined that claim 24 is not invalid [\*34] for lack of an adequate written description.

B.

[HN17] The patent specification must disclose information sufficient to enable those skilled in the art to make and use the claimed invention. 35 U.S.C. § 112 P 1. That some experimentation is required to practice the claimed invention is permissible, so long as it is not undue. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). Enablement under 35 U.S.C. § 112, P 1, is a question of law that this court reviews de novo. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed. Cir. 1986). This court reviews a jury's underlying factual determinations related to enablement for substantial evidence. *Mitsubishi Elec. Corp. v. Ampex Corp.*, 190 F.3d 1300, 1309, 51 USPQ2d 1910, 1916 (Fed. Cir. 1999).

FPS contends that the specification does not enable one of ordinary skill in the art to lift eggs from a moving conveyor belt without undue experimentation. Nevertheless, FPS presented no record evidence recounting the amount of experimentation one of skill in the art would [\*35] require to develop the conveyor lifting system of the Moba Omnia in view of the '505 patent disclosure. Rather, FPS asked the jury and asks this court to draw the inference of undue experimentation based on limited general testimony of the development of that conveyor lifting mechanism taken separate from the disclosure of the '505 patent. The trial court found that evidence insufficient to prove undue experimentation. Hence, this court holds that substantial evidence supports the verdict of the jury that claim 24 was not invalid for lack of enablement.

C.

[HN18] Anticipation under 35 U.S.C. § 102 requires that a single prior art reference disclose each and every limitation of the claimed invention. *Electro Med Sys. S.A. v. Cooper Life Sci.*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). This court reviews a jury's conclusions on anticipation for substantial evidence. *Advanced Display Sys.*, 212 F.3d at 1281.

FPS argues that claim 24 of the '505 patent is anticipated by its own Moba prior art machines, such as the Types 4-9 or Type 68 machines that provided the basis for the Omnia lifting mechanism. Nevertheless, as [\*36] was testified by FPS's own expert witness, Dr. Kirk, those prior art Moba machines do not continuously advance eggs through weighing stations while simultaneously weighing the eggs, as is required by claim 24. Hence, this court finds that claim 24 is not anticipated as a matter of law by the asserted Moba prior art machines.

In sum, because substantial evidence supports the jury verdict that claim 24 of the '505 patent is not

invalid, this court affirms that portion of the district court judgment.

#### CONCLUSION

The district court correctly determined that substantial evidence supports the jury verdict that FPS does not infringe claim 28 of the '494 patent. This court affirms, therefore, the district court's denial of Diamond's JMOL motion on that issue. Because FPS does not infringe the '494 patent, this court makes no determination as to that patent's validity. On claim 24 of the '505 patent, this court remands for further determination of whether FPS induced its customers to infringe under a correct reading of that claim. This court reverses, therefore, the district court's denial of JMOL on those issues and remands. Because substantial evidence supports the validity of properly [\*37] construed claim 24, this court affirms that portion of the district court's judgment.

#### COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED

#### CONCURBY:

RADER; BRYSON

#### CONCUR:

RADER, Circuit Judge, concurring.

This case reveals a distinct institutional difference between the United States Court of Appeals for the Federal Circuit and the other twelve circuits. Whenever a Federal Circuit panel makes an error interpreting the patent code, every district court in the nation, and even every later Federal Circuit panel, is obliged to follow and perpetuate the error. Even the Supreme Court has difficulty identifying errors for correction because this court's national jurisdiction requires universal application of a mistake. This particular Moba case does not originate, but perpetuates such an error.

This mistake misapplies both the statutory law and the policy underlying United States patent law. Specifically, this court - contrary to the statute and its own thirty-year body of case law - applies the written description doctrine beyond the purpose for which the doctrine was created, namely priority protection. By making written description a free-standing [\*38] disclosure doctrine, this court produces numerous unintended and deleterious consequences.

#### I.

This case illustrates some of the unintended consequences of this judge-made doctrine. Each time a claim encompasses more than the preferred embodiment of the invention described in the specification, a defendant can assert that the patent is invalid for failure to describe the entire invention. Under the expanded written description doctrine, every claim construction argument could conceivably give rise to a validity challenge as well. In this case, for instance, FPS Food Processing Systems, Inc. ("FPS") argues if claim 24 of the '505 patent encompasses lifting eggs from a moving conveyor, as this court has determined, then claim 24 must be invalid because the '505 patent specification discloses no such conveyor mechanism. FPS's routine claim construction argument becomes a validity challenge under the non-statutory doctrine created in the Lilly case. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Fortunately, this court did not fall for FPS's argument.

Unfortunately, however, this court is not the only judicial actor [\*39] that must deal with the unintended consequences of the Lilly doctrine. Because FPS argued that the specification did not disclose some feature of the claimed invention, the trial court had to take extensive testimony and ask a jury to speculate whether one of skill in the art would have known that the inventor "possessed" the full invention.

The trial court faced even greater confusion because FPS also asserted that the specification does not enable the claimed invention. Thus, the trial court asked this jury to determine whether one of skill in the art would have been able to make and use the invention based on the patent's specification. Then the trial court asked to jury to look at the specification again to determine whether the inventor "possessed" the invention. Thus, this jury faced the cumbersome task of separating two doctrines for sufficiency of disclosure in a patent. Under Federal Circuit case law, FPS asked this jury to decide that the patent's disclosure can enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention. Puzzling. Moreover, the trial court had to give [\*40] separate instructions and entertain separate witnesses on these inseparable patent rules to ensure full disclosure. The Lilly doctrine simply makes no sense in this context. In fact, outside its proper context of policing priority, it never makes sense but compounds the confusion, increases the chances for error, and augments the expense of the trial process.

#### II.

The Patent Act refers to "a written description" in 35 U.S.C. § 112, P 1:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, P 1 (2000) (emphasis added). The language of § 112, P 1 indicates that a patent will contain an adequate description if it provides enough information to enable a person skilled in the art to make and use the invention. Any disclosure that enables one to make and use [\*41] the invention also, by definition, also shows that the inventor was in possession of that full invention. Consequently, the erroneous written description requirement of Lilly case lacks both a statutory and a logical foundation.

This origins of the Lilly error have been explored at length in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609, 1628 (app.) (Fed. Cir. 2002) (rehearing en banc denied) (Rader, J., dissenting). Before 1967, written description was not a requirement separate from enablement. In *In re Ruschig*, this court's predecessor court created a new written description requirement for the sole purpose of enforcing priority issues. See *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (CCPA 1967). The court in *Ruschig* used § 112, P 1 to reject later-drafted claims that encompassed subject matter not disclosed by the original claims and specification. A section of title 35, specifically § 132, directly prohibits the addition of new matter to a disclosure, either in the claims or the rest of the patent application. Nonetheless, this court's predecessor decided to use § 112 to prevent the addition [\*42] of new matter to claims, rather than the specific provisions of § 132. This extra license with the language of title 35 did no harm because the Court of Customs and Patent Appeals recognized "that a rejection of an amended claim under § 132 is equivalent to a rejection under § 112, first paragraph." *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 325 (CCPA 1981).

Thus, from 1967 until 1997, the new matter doctrine, cloaked either in the specific language of § 132 or the innovative new reading of § 112, operated only to determine whether new claim language deserved priority back to the patent's original filing date. In other words,

when the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the patent application

when filed as the invention of the patents. That is the essence of the so-called 'description requirement' of § 112, first paragraph.

*In re Wright*, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (emphasis added). [\*43]

The new matter doctrines did not extend beyond priority issues because § 112 already supplies enablement to ensure that an inventor adequately describes the invention in exchange for temporary rights of exclusivity. For over thirty years, this court and its predecessor understood this basic principle of patent law and confined the written description doctrine to its purpose - policing priority of invention. n1

n1 See generally *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609, 1628 (Fed. Cir. 2002) (app.) (rehearing en banc denied) (Rader, J., dissenting) (quoting from every written description case, except Lilly, to show they only employed the doctrine to police priority).

In 1997, this court inexplicably wrote a new disclosure requirement, found nowhere in title 35, and attributed that new requirement to the written description doctrine. This new disclosure doctrine, applied so far only to biotechnology cases, requires a nucleotide-by-nucleotide recitation of the structure [\*44] of a biotechnological invention. *Lilly*, 119 F.3d at 1567. Ironically, this court could have reached the same result in Lilly without making a new disclosure rule. Under the statute's enablement rule, this court would have also determined that the invention was not sufficiently disclosed. n2 Instead, this court presumed to create another doctrine for sufficiency of disclosure. Although characterized as a written description doctrine, the Lilly rule cannot in fact trace its origin to the statute or to any prior case. See generally *Enzo*, 63 USPQ2d at 1627-29.

n2 U.S. Patent No. 4,652,525, at issue in Lilly, claimed priority to a parent application filed in 1977. The art of biotechnology was in its early stages in 1977. Under a proper enablement analysis, the simple disclosure of human insulin cDNA in the '525 patent would have failed to enable a person skilled in the art in 1977 to practice the claimed invention. Thus, the claims at issue would have been found invalid for lack of enablement.

[\*45]

Confusing the Lilly disclosure doctrine with the traditional written description doctrine, this court has stated that written description is separate from enablement. See *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Of course, this proposition is true with respect to the traditional written description/new matter doctrine. On the other hand, the only way to distinguish the Lilly rule from enablement is to construe Lilly as requiring more disclosure than necessary to enable one of skill in the art to make and use the invention, a "super-enablement" standard.<sup>n3</sup> Interpreting Lilly in those terms, however, presents severe consequences for biotechnology. For biotechnological inventions, Lilly purports to require the recitation, nucleotide by nucleotide, of the entire sequence of a new protein or composition. This non-statutory rule jeopardizes the validity of many inventions in biotechnology patented from the advent of the biotech era in the late 1970s. Before judicial creation of the Lilly rule in 1997, no inventor could have foreseen that the Federal Circuit would make a super-enablement rule. Without [\*46] any way to redraft issued patents to accommodate the new rule, a large number of patents in the field of biotechnology face serious and unavoidable validity challenges.

<sup>n3</sup> See Rai, Arti, "Intellectual Property Rights in Biotechnology: Addressing New Technology" 34 *Wake Forest L. Rev.* 827, 834-35 (Fall, 1999) ("the Lilly court used the written description requirement as a type of elevated enablement requirement."); Sampson, Margaret, "The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology" 15 *Berkley Tech. L.J.* 1233, 1262 (Fall 2000) ("The primary argument against the Federal Circuit's heightened written description requirement for biotechnological invention is that ... it also 'reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research.'"); Mueller, Janice M., "The Evolving Application of the Written Description Requirement to Biotechnological Inventions" 13 *Berkeley Tech. L.J.* 615, 617 (Spring 1998) ("The Lilly decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding. The Lilly court elevates written description to an effective 'super enablement' standard ....").

[\*47]

Even if a drafter of biotechnological patents now knows the new law, compliance may tax a drafter beyond reasonable limits. A new protein or other DNA-related discovery may contain a chain of hundreds of amino acids. Many of the amino acids in the chain have substitutes that may take their place without altering the functional properties of the protein. Consequently, a "precise definition" <sup>n4</sup> of the new protein, as required by Lilly, apparently requires tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source.

<sup>n4</sup> See *Eli Lilly*, 119 F.3d at 1566 (citing the "precise definition" standard of *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

This burdensome disclosure standard is tantamount to requiring disclosure, for a new software invention, of the entire source code, symbol by symbol, including all source code permutations that would not alter [\*48] the function of the software. Ironically, the Federal Circuit has expressly rejected such a requirement for software inventions, but apparently enforces the requirement for biotechnology. See e.g. *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990) (overturning a finding that a patent did not adequately disclose "batching" software). This discrepancy emphasizes another problematic aspect of the Lilly doctrine. That is, it imposes a different disclosure standard for biotechnology than for computer technology. Despite the technology-neutral language of the *Patent Act*, the Lilly rule imposes technology-specific requirements.

Returning to the consequences of the Lilly rule for biotechnology, the burdens of this elevated "precise definition" standard unnecessarily increase the cost and time required to prepare and prosecute a biotechnology patent. Moreover, university inventors and non-corporate biotechnologists must endure significant expense and delay to acquire the sequence of a potential invention for disclosure under the Lilly rule. Sequencing is very expensive. Consequently, the Lilly rule can also have the unintended [\*49] consequence of pricing non-corporate inventors out of the inventive market for biotechnology.

### III.

Fortunately, the viability of the Lilly rule is on the decline. After *Enzo*, this court recognized "that Ely Lilly did not hold that all functional descriptions of genetic

material necessarily fails as a matter of law to meet the written description requirement, rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." *Amgen*, 314 F.3d at 1332, 1361 (dissent: "The majority ... verges on confining Ely Lilly to its facts.").

In this case, as in *Enzo*, the court explained that the written description requirement is satisfied when "one of skill in the art would discern possession of the invention at the time of filing." Indeed, the *Enzo* court struggled to distinguish the so-called written description requirement from enablement. In reversing its original decision that deposits of biological material do not satisfy the written description requirement, the *Enzo* panel cited cases that found that such deposits satisfy the enablement requirement.<sup>n5</sup> [\*50] In other words, because Lilly did in fact compel the result of the original *Enzo* panel, the court on reconsideration had to concede that deposited material satisfies the Lilly standard if it meets the enablement standard.

<sup>n5</sup> See *Enzo*, 296 F.3d at 1325 ("Whether reference to a deposit of a nucleotide sequence may adequately describe that sequence is an issue of first impression in this court. In light of the history of biological deposits for patent purposes [and] the goals of patent law ... we hold that reference in the specification to a deposit in a public depository ... constitutes an adequate description of the deposited material. . . . The practice of depositing biological material arose primarily to satisfy the enablement requirement of § 112, P 1") (citing *In re Argoudelis*, 58 C.C.P.A. 769, 434 F.2d 1390, 168 USPQ 99, 100 (CCPA 1970) (finding that making the biological material accessible to the public enabled the public to make and use the claimed antibiotics)).

[\*51]

With some understanding of the difficulties and redundancy of the Lilly rule, the Federal Circuit has begun to convert it into the enablement doctrine with a different label. Unfortunately that leaves trial courts in the fix that the trial court faced in this case - presenting the jury two disclosure doctrines with apparently overlapping requirements. After all, to enable is to show possession, and to show possession is to enable.<sup>n6</sup>

<sup>n6</sup> Patent scholars have encouraged this court to "resist the narcotic of the written description requirement and redirect [its] energies

towards refining the enablement concept, particularly as it correlates to claim scope." Janis, Mark D., "On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)" 2 *Wash. U. J. L. & Pol'y* 55, 62, 107 (2000) ("the fault [for the confusion about the standard for patent disclosure] lies in the courts' hesitancy to explore the power of the enablement requirement.").

[\*52]

#### IV.

In sum, the Lilly rule is not just a mere one-time mistake. It defies over thirty years of case law. It finds no specific support in any statutory language. It creates a technology-specific rule in a technology-neutral statute. It distorts the statute's rules for adequate disclosure of inventions. It complicates biotechnology patent drafting to the point of near impossibility and invites invalidating mistakes. It prices non-corporate inventors out of some biotechnological invention markets. Last, but not least, it burdens both trial and appellate courts with unnecessary and confusing procedures in otherwise simple cases like this one.

Of course, this court should recognize and prevent, rather than ignore and create, mistakes in the interpretation of the *Patent Act*. In the rare event that this court makes this type of error, this Circuit has a unique obligation to swiftly pursue en banc correction. Unlike regional circuits, this court cannot rely on circuit splits to identify an issue for Supreme Court correction. Moreover this court's jurisdiction over patents requires every trial court and this court itself to multiply this type of error until corrected. Accordingly, [\*53] this court has a greater responsibility to pursue en banc correction of serious errors in interpretations of the *Patent Act*, such as the Lilly rule.

Alternatively, as indicated in Judge Bryson's concurring opinion, the problem in this area of the law may lie in the line of cases stemming from the *Ruschig* case. In that context, I agree that all priority issues can be more than adequately resolved under the new matter doctrine in 35 U.S.C. § 132.

BRYSON, Circuit Judge, concurring.

Having been a member of the panel that decided *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), I write to make a single point with regard to the court's decision in that case. Lilly has been criticized as departing from prior law by applying the written

description requirement for a purpose other than to police priority. Setting aside the question whether the disclosure requirement imposed in Lilly was unduly stringent, a point that Judge Rader addresses in his concurring opinion, I do not believe that Lilly constituted a departure from prior law when it applied the written [\*54] description requirement in a non-priority context.

*In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), held that 35 U.S.C. § 112, paragraph 1, contains a written description requirement that is separate from the enablement requirement found in the same paragraph. That interpretation of the statute may or may not have been correct--there is something to be said for either side of that question of statutory construction. But there is no question that Ruschig and subsequent decisions have held that written description and enablement are separate statutory requirements, and that written description is not simply a facet of enablement. Judge Rader acknowledges as much, but argues that as long as the Ruschig doctrine was confined to cases involving priority disputes, that reading of the statutory language worked no particular mischief, as it was simply redundant of the statutory prohibition against new matter in 35 U.S.C. § 132. The problem, as I see it,

is that if it is correct to read *section 112* as containing a separate written description requirement, it is difficult to find a principled basis [\*55] for restricting that requirement to cases involving priority disputes. There is no language in *section 112* that would support such a restriction, and I am unaware of any other basis for construing the statute in that fashion, unless we are simply to announce that the Ruschig cases will be tolerated, but must be limited to their facts. Put another way, if the Ruschig line of cases is sound as a matter of statutory construction, it is difficult to see why that construction does not apply equally in the Lilly non-priority context.

Perhaps the entire line of cases stemming from Ruschig is wrong, and perhaps we should at some point address that question en banc. I take no position on that issue at this juncture. I think it is worth pointing out, however, that the real question raised by Judge Rader's statutory analysis is not whether Lilly was an unwarranted departure from the Ruschig line of cases, but whether that entire line of cases is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1.



Creation date: 09-04-2003  
Indexing Officer: NNGUYEN7 - NAM NGUYEN  
Team: OIPEBackFileIndexing  
Dossier: 09707468

Legal Date: 07-28-2003

No.	Doccode	Number of pages
1	LET.	2
2	A...	1
3	CLM	3
4	REM	9
5	XT/	1

Total number of pages: 16

Remarks:

Order of re-scan issued on .....